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Research Section

Evaluation of the potential effects of ingredients added to cigarettes. Part 1: Cigarette design, testing approach, and review of results[☆]

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Abstract

A testing program was designed to evaluate the potential effects of 333 ingredients added to typical commercial blended test cigarettes on selected biological and chemical endpoints. Ingredients were incorporated into the test cigarettes as they are normally used in the manufacturing process. The studies performed included a bacterial mutagenicity screen (Ames assay), a mammalian cell cytotoxicity assay (neutral red uptake), determination of smoke chemical constituents, and a 90-day nose-only smoke inhalation study in rats. Three pairs of test cigarettes were produced, each containing one of three different groups of ingredients. In each pair, one of the cigarettes contained the normal approximate use level of the ingredients (low-level) and the other a 1.5–3 multiple of the normal use level (high-level). Analysis of the test cigarettes for selected ingredients or markers indicated that the target application rates were achieved and that the cigarettes had been manufactured as intended. Evaluation of cigarette performance indicated that the addition of the ingredients at high levels did not significantly alter the burning characteristics of the test cigarettes. Specific details of the individual studies conducted as part of an ingredient evaluation program are discussed in Parts 2–4 of this publication series (Food and Chemical Toxicology, 2002, 40, 93–104; Food and Chemical Toxicology, 2002, 40, 105–111; Food and Chemical Toxicology, 2002, 40, 113–131). The results of the smoke chemistry studies indicated a reduction in the majority of the smoke constituents and a few isolated instances of increases when compared to the control cigarettes. These smoke chemistry changes, while statistically significant, were not supported by any significant alteration in the biological effects of cigarette smoke normally seen with the bacterial mutagenicity assay, cytotoxicity assay or subchronic inhalation study. Based on the results of these studies, it can be concluded that these ingredients added to tobacco do not add significantly to the overall toxicity of cigarettes. © 2001 Elsevier Science Ltd. All rights reserved.

Keywords: Ingredient; Tobacco; Cigarette smoke; Toxicity; Inhalation

1. Introduction

Commercial cigarettes are made by blending various types of tobacco leaf (bright, Burley and oriental) and processed tobacco (expanded, reconstituted and stems). During the blending and processing of tobacco, humectants such as glycerol and propylene glycol are added to increase the moisture holding capacity of the tobacco and aid in processing, while flavor ingredients are used to complement the subjective characteristics of the smoke.

Abbreviations: DAP, diammonium hydrogen phosphate; FEMA, Flavor and Extract Manufacturers Association; FTC, Federal Trade Commission; GRAS, generally recognized as safe; IARC, International Agency for Research on Cancer; ISO, International Organization for Standardization; TPM, total particulate matter

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These ingredients include non-volatile materials such as sugars and licorice, and highly volatile aromatic materials such as menthol. Other kinds of ingredients used to enhance the flavor of tobacco smoke include foods such as chocolate and cocoa, and spices such as vanilla, nutmeg and ginger. Most of the volatile ingredients applied to cigarette tobacco would not be expected to pyrolyse extensively during smoking and would be expected to transfer intact to the smoke (Green et al., 1989).

Cigarette ingredient regulation varies around the world. The United Kingdom has a list of permitted cigarette additives (Report of the Independent Scientific Committee on Smoking and Health, 1988), while the German Tobacco Ordinance lists permitted tobacco additives and specifically excludes certain fragrances and flavors. In 1984, the US Congress amended the Federal Cigarette Labeling and Advertising Act to require cigarette manufacturers to submit to the Secretary of Health and Human Services a list of all ingredients